

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
AUSTIN DIVISION**

GARY ZAGAMI, derivatively on behalf of  
CASSAVA SCIENCES, INC.,

Plaintiff,

v.

REMI BARBIER, ERIC J. SCHOEN, JAMES  
W. KUPIEC, NADAV FRIEDMANN,  
MICHAEL MARSMAN, ROBERT Z. GUSSIN,  
MICHAEL J. O'DONNELL, SANFORD R.  
ROBERTSON, and PATRICK J. SCANNON,

Defendants,

and

CASSAVA SCIENCES, INC.,

Nominal Defendant.

Case No.: 1:21-cv-998

**DEMAND FOR JURY TRIAL**

**VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT**

**INTRODUCTION**

Plaintiff Gary Zagami ("Plaintiff"), by Plaintiff's undersigned attorneys, derivatively and on behalf of Nominal Defendant Cassava Sciences, Inc. ("Cassava" or the "Company"), files this Verified Shareholder Derivative Complaint against Defendants Remi Barbier, Eric J. Schoen, James W. Kupiec, Nadav Friedmann, Michael Marsman, Robert Z. Gussin, Michael J. O'Donnell, Sanford R. Robertson, and Patrick J. Scannon (collectively, the "Individual Defendants" and with Cassava, "Defendants") for breaches of their fiduciary duties as directors, and/or officers of Cassava, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and for contribution under Sections 10(b) and 21D of the Exchange Act. As for Plaintiff's complaint

against the Individual Defendants, Plaintiff alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Cassava, legal filings, news reports, securities analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Cassava's directors and officers from September 14, 2020 through August 27, 2021, both dates inclusive (the "Relevant Period").

2. Cassava is a Delaware biotechnology corporation based in Austin, Texas, that develops drugs for neurodegenerative diseases. Its lead therapeutic product candidate is "simufilam" which is a treatment for Alzheimer's disease. Its lead investigational diagnostic product is "SavaDx," a blood-based diagnostic test to detect Alzheimer's. Simufilam is designed to target a protein in the brain, filamin A ("FLNA"), and reverts it to a healthy conformation, combatting the effects of altered FLNA.

3. Currently, the Company has no source of revenue, and therefore its overall financial success depends largely on it successfully getting regulatory approval for its lead product candidates in order to get them to market.

4. Beginning September 14, 2020, and throughout the Relevant Period, the Individual Defendants caused the Company to submit manipulated data to the U.S. Food and Drug

Administration (“FDA”) and made, or caused the Company to make, materially false and misleading statements to the investing public concerning the accuracy and reliability of data the Company was holding out as demonstrating simufilam’s efficacy.

5. However, during this time, the Individual Defendants failed to disclose that the data being presented to the public had been manipulated to show simufilam was more effective than it actually was.

6. The truth began emerging on August 24, 2021, after the market had closed, when a citizen petition submitted to the FDA noted that the data Cassava was presenting on simufilam’s effectiveness contained “a series of anomalies that are suggestive of systemic data manipulation and misrepresentation[,]” and that the Company’s practice of studying “Simufilam’s effects in experiments conduct on *postmortem human brain tissue* . . . defies logic, and the data presented again have hallmarks of manipulation.” (Emphasis added.)

7. The next day, August 25, 2021, before the market opened, the Company issued a response, defending itself on many grounds, and in part by noting that “Cassava Sciences’ plasma p-tau data from Alzheimer’s patients was generated by Quanterix Corp., an independent company, and presented at the recent Alzheimer’s Association International Conference[.]”

8. Despite the Company’s spin, the market received the two-days’ news negatively, and the price per share of the Company’s common stock dropped from \$117.83 at close on August 24, 2021, to close August 25, 2021 at \$80.86. This \$36.97 decline marked approximately a 31.4% one-day decrease in value.

9. However, the full truth then emerged on August 27, 2021, Quanterix Corp. (“Quanterix”), put out its own statement in response to Cassava, noting that “Quanterix’[s] sole responsibility with regard to this clinical study was to perform sample testing” and that “Quanterix

or its employees did not interpret the test results or prepare the data charts presented by Cassava at the Alzheimer's Association International Conference (AAIC) in July 2021 or otherwise.”

10. On this news, the Company's share price declined by \$12.51 per share—approximately 17.7%—from its August 26, 2021 closing price of \$70.85 per share to close August 27, 2021 at \$58.34.

11. During the Relevant Period, the Individual Defendants breached their fiduciary duties by personally making and/or causing the Company to make to the investing public a series of materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements that failed to disclose, *inter alia*, that: (1) the quality and integrity of the data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; (5) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (6) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (7) the Company failed to maintain internal controls. As a result of the foregoing, Cassava's public statements regarding simufilam were materially false and misleading at all relevant times.

12. The Individual Defendants also breached their fiduciary duties by causing the Company to submit to the FDA data that had been manipulated to make simufilam appear more

effective than it was.

13. Moreover, the Individual Defendants breached their fiduciary duties by failing to correct and/or causing the Company to fail to correct these false and misleading statements and omissions of material fact. Additionally, in breach of their fiduciary duties, the Individual Defendants caused the Company to fail to maintain adequate internal controls.

14. In light of the Individual Defendants' misconduct—which has subjected the Company, and certain of its directors and officers to three federal securities fraud class action lawsuits pending in the United States District Court for the Western District of Texas (the "Securities Class Actions"), and which has further subjected the Company to the need to undertake internal investigations, the need to implement adequate internal controls, losses from the waste of corporate assets, and losses due to the unjust enrichment of Individual Defendants who were improperly overcompensated by the Company and/or who benefitted from the wrongdoing alleged herein—the Company will have to expend many millions of dollars.

15. The Company has been substantially damaged as a result of the Individual Defendants' knowing or highly reckless breaches of fiduciary duty and other misconduct.

16. In light of the breaches of fiduciary duty engaged in by the Individual Defendants, most of whom are the Company's current directors, of the collective engagement in fraud and misconduct by the Company's directors, of the substantial likelihood of the directors' liability in this derivative action and of certain directors' and officers' liability in the Securities Class Actions, and of their not being disinterested and/or independent directors, a majority of the Company's Board of Directors (the "Board") cannot consider a demand to commence litigation against themselves on behalf of the Company with the requisite level of disinterestedness and independence.

### **JURISDICTION AND VENUE**

17. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act (15 U.S.C. § 78n(a)(1)), Rule 14a-9 of the Exchange Act (17 C.F.R. § 240.14a-9), Section 10(b) of the Exchange Act (15 U.S.C. § 78j(b)), and Section 21D of the Exchange Act (15 U.S.C. § 78u-4(f)). Plaintiff's claims also raise a federal question pertaining to the claims made in the Securities Class Actions based on violations of the Exchange Act.

18. This Court also has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds the sum or value of \$75,000 exclusive of interest and costs.

19. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

20. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

21. Venue is proper in this District because the alleged misstatements and wrongs complained of herein entered this District, the Defendants have conducted business in this District, and Defendants' actions have had an effect in this District. In addition, the Company's principal executive offices are located in this District.

### **PARTIES**

#### **Plaintiff**

22. Plaintiff is a current shareholder of Cassava. Plaintiff has continuously held Cassava common stock at all relevant times.

23. Plaintiff is a citizen of Florida.

**Nominal Defendant Cassava**

24. Cassava is a Delaware corporation with its principal executive offices at 7801 N. Capital of Texas Highway, Suite 260, Austin, Texas 78731. Cassava's shares trade on the NASDAQ Capital Market ("NASDAQ") under the ticker symbol "SAVA."

**Defendant Barbier**

25. Defendant Remi Barbier ("Barbier") is the Company's President, Chief Executive Officer ("CEO"), and Chairman of the Board, and has served in all three roles since he founded the Company in May 1998. According to the Company's Schedule 14A filed with the SEC on March 31, 2021 (the "2021 Proxy Statement"), as of March 16, 2021, Defendant Barbier beneficially owned 2,047,449 shares of the Company's common stock, representing 5.0% of the Company's outstanding common stock. Given that the price per share of the Company's common stock at the close of trading on March 16, 2021 was \$52.16, Defendant Barbier owned approximately \$107 million worth of Cassava stock.

26. For the fiscal year ended December 31, 2020 (the "2020 Fiscal Year"), Defendant Barbier received \$936,120 in total compensation from the Company, including a salary of \$920,000 and \$16,120 in all other compensation.

27. Upon information and belief, Defendant Barbier is a citizen of Texas.

28. The 2021 Proxy Statement stated the following about Defendant Barbier:

*Remi Barbier*, the Company's founder, has served as President, Chief Executive Officer and Chairman of the Board of Directors since the Company's inception in May 1998. Prior to that time, Mr. Barbier helped in the growth or founding of Exelixis Inc. and ArQule, Inc., both publicly-traded drug development companies, and EnzyMed, Inc., a chemistry company sold to Albany Molecular Research, Inc. Mr. Barbier is a trustee emeritus of the Carnegie Institute of Washington and the Santa Fe Institute and is on the Advisory Board of the University of California Institute for Quantitative Biosciences and BioVentures LLC, a life science incubator at the University of Arkansas for Medical Sciences. Mr. Barbier received his B.A. from Oberlin College and his M.B.A. from the University of Chicago.

**Defendant Schoen**

29. Defendant Eric J. Schoen (“Schoen”) has served as the Company’s Chief Financial Officer (“CFO”) since October 2018. According to the 2021 Proxy Statement as of March 16, 2021, Defendant Schoen beneficially owned 58,550 shares of the Company’s common stock. Given that the price per share of the Company’s common stock at the close of trading on March 16, 2021 was \$52.16, Defendant Schoen owned approximately \$3.1 million worth of Cassava stock.

30. For the 2020 Fiscal Year, Defendant Schoen received \$251,932 in compensation from the Company, including \$250,000 in salary and \$1,932 in all other compensation.

31. Upon information and belief, Defendant Schoen is a citizen of Texas.

32. The 2021 Proxy Statement stated the following about Defendant Schoen:

*Eric Schoen* has served as Chief Financial Officer since October 2018. Prior to joining the Company, Mr. Schoen served in numerous financial leadership roles. Most recently, he served as Vice President, Senior Vice President, Finance and Chief Accounting Officer of Aspria Women’s Health Inc. (formerly Vermillion, Inc.), a publicly-held women’s health company, from 2011 to 2017. Mr. Schoen also began his career and spent nine years with PricewaterhouseCoopers in the audit and assurance, transaction services and global capital markets practices. Mr. Schoen received his B.S. in Finance from Santa Clara University.

**Defendant Kupiec**

33. Defendant James W. Kupiec (“Kupiec”) has served as the Company’s Chief Clinical Development Officer (“CCDO”) since January 2021.

34. Upon information and belief, Defendant Kupiec is a citizen of Texas.

35. The 2021 Proxy Statement stated the following about Defendant Kupiec:

*James W. Kupiec, M.D.* has served as Chief Clinical Development Officer since January 2021. Dr. Kupiec joined the Company after three decades of drug development experience at Pfizer, Sanofi and Ciba-Geigy. Dr. Kupiec previously served as Vice President, Global Clinical Leader for Parkinson’s Disease and Clinical Head of the Neuroscience Research Unit for Pfizer, Inc., in Cambridge,



MA. He joined Pfizer in 2000 after seven years with Sanofi, and two years with Ciba-Geigy Pharmaceuticals. During his 17-year career at Pfizer, Dr. Kupiec had extensive governance, business development, alliance and leadership responsibilities. Dr. Kupiec earned his BS with Honors in Biochemistry at Stony Brook University and his MD from the Albert Einstein College of Medicine. He completed his residency training at the Strong Memorial Hospital, University of Rochester School of Medicine, and is certified by the American Board of Internal Medicine. He served as an investigator on many clinical trials before transitioning to the pharmaceutical industry.

**Defendant Friedmann**

36. Defendant Nadav Friedmann (“Friedmann”) has served as a Company director since September 1998 and as Chief Medical Officer (“CMO”) at the Company since 2001. According to the 2021 Proxy Statement, as of March 16, 2021, Defendant Friedmann beneficially owned 572,076 shares of the Company’s common stock, representing 1.4% of the Company’s outstanding shares. Given that the price per share of the Company’s common stock at the close of trading on March 16, 2021 was \$52.16, Defendant Friedmann owned approximately \$29.8 million worth of Cassava stock.

37. For the 2020 Fiscal Year, Defendant Friedmann received \$345,000 in compensation from the Company, all in salary.

38. Upon information and belief, Defendant Friedmann is a citizen of Texas.

39. The 2021 Proxy Statement stated the following about Defendant Friedmann:

*Nadav Friedmann, Ph.D., M.D.* has served as a director since September 1998. Dr. Friedmann has served as Chief Medical Officer since 2001. Dr. Friedmann was previously President and CEO of Daiichi Pharmaceutical Corporation. Dr. Friedmann has served as Vice President, Clinical Research at Xoma Corporation, and held various senior leadership positions with Johnson & Johnson, including Head of its Biotechnology Research Center. Dr. Friedmann received his M.D. from the Albert Einstein College of Medicine and his Ph.D. in Biochemistry from the University of California, San Diego.

**Defendant Marsman**

40. Defendant Michael Marsman (“Marsman”) serves as a consultant to the Company

and prior to that as Senior Vice President of Regulatory Affairs for the Company since April 2015.

41. Upon information and belief Defendant Marsman is a citizen of Texas.

42. The April 23, 2015 press release that announced Defendant Marsman was joining the Company, then-known as Pain Therapeutics, Inc., stated the following of him:

Pain Therapeutics, Inc. (Nasdaq:PTIE), a clinical-stage biopharmaceutical company, announced the appointment of Michael Marsman, Pharm.D., as Senior Vice President, Regulatory Affairs. Dr. Marsman will be responsible for developing and implementing regulatory strategies to gain drug approvals. He previously led regulatory affairs at Pain Therapeutics for nearly a decade before leaving in 2012 amid a corporate reorganization.

“We’re honored Dr. Marsman has decided to rejoin our management team,” said Remi Barbier, Chairman, President & CEO. “I believe his appointment is testament to our potential for growth.”

“I’m excited by what I see here at Pain Therapeutics,” said Dr. Marsman, SVP, Regulatory Affairs. . . .

Dr. Marsman most recently served as V.P. Regulatory Affairs at Impax Laboratories (Nasdaq:IPXL). Before that, he led Regulatory Affairs at Pain Therapeutics for nearly ten years. Before that he also held senior positions at Millennium Pharmaceuticals, COR Therapeutics, Sequus Pharmaceuticals and Syntex, where he had shared responsibility for the regulatory approval of several high profile drugs.

### **Defendant Gussin**

43. Defendant Robert Z. Gussin (“Gussin”) has served as a Company director since March 2003. He also serves as a member of both the Audit Committee and Compensation Committee. According to the 2021 Proxy Statement, as of March 16, 2021, Defendant Gussin beneficially owned 119,225 shares of the Company’s common stock. Given that the price per share of the Company’s common stock at the close of trading on March 16, 2021 was \$52.16, Defendant Gussin owned approximately \$6.2 million worth of Cassava stock.

44. For the 2020 Fiscal Year, Defendant Gussin received \$75,924 in compensation from the Company, all in option awards.

45. Upon information and belief, Defendant Gussin is a citizen of New York.

46. The 2021 Proxy Statement stated the following about Defendant Gussin:

*Robert Z. Gussin, Ph.D.* has served as a director since March 2003. Dr. Gussin worked at Johnson & Johnson for 26 years, most recently as Chief Scientific Officer and Corporate Vice President, Science and Technology from 1986 through his retirement in 2000. Dr. Gussin served on the board of directors of Duquesne University and the advisory boards of the Duquesne University Pharmacy School and the University of Michigan Medical School Department of Pharmacology. Dr. Gussin received his B.S. and M.S. degrees and D.Sc. with honors from Duquesne University and his Ph.D. in Pharmacology from the University of Michigan, Ann Arbor.

**Defendant O'Donnell**

47. Defendant Michael J. O'Donnell ("O'Donnell") has served as a Company director since June 1998. According to the 2021 Proxy Statement, as of March 16, 2021, Defendant O'Donnell beneficially owned 83,223 shares of Company common stock. Given that the price per share of the Company common stock was \$52.16 at the close of trading on March 16, 2021, Defendant O'Donnell owned approximately \$4.3 million worth of Cassava common stock.

48. Upon information and belief, Defendant O'Donnell is a citizen of California.

49. The 2021 Proxy Statement stated the following about Defendant O'Donnell:

*Michael J. O'Donnell, Esq.* has served as a director since June 1998. Mr. O'Donnell has been a member of the law firm of Morrison & Foerster LLP since 2011. Morrison & Foerster LLP is the Company's corporate counsel and provides legal services to the Company. Mr. O'Donnell serves as corporate counsel to numerous public and private biopharmaceutical and life sciences companies. Previously, Mr. O'Donnell was a member of Wilson Sonsini Goodrich & Rosati. Mr. O'Donnell received his J.D., cum laude, from Harvard University and his B.A. from Bucknell University, summa cum laude.

**Defendant Robertson**

50. Defendant Sanford R. Robertson ("Robertson") has served as a Company director since September 1998. He serves as a member on each of the Audit Committee, the Compensation Committee, and the Nominating and Governance Committee. In addition, he serves as Lead

Director. According to the 2021 Proxy Statement, as of March 16, 2021, Defendant Robertson beneficially owned 1,027,943 shares of Company common stock. Given that the price per share of the Company common stock was \$52.16 at the close of trading on March 16, 2021, Defendant Robertson owned approximately \$53.6 million worth of Cassava common stock.

51. For the 2020 Fiscal Year, Defendant Robertson received \$75,924 in compensation from the Company, all in options awards.

52. Upon information and belief, Defendant Robertson is a citizen of California.

53. The 2021 Proxy Statement stated the following about Defendant Robertson:

*Sanford R. Robertson* has served as a director since September 1998. Mr. Robertson has been a partner of Francisco Partners, a technology buyout fund, since 1999. Prior to founding Francisco Partners, Mr. Robertson was the founder and chairman of Robertson, Stephens & Company, a technology investment bank sold to BankBoston in 1998. Mr. Robertson is the lead director of Salesforce.com, a publicly-held provider of enterprise cloud computing applications. Mr. Robertson received his B.A. and M.B.A. degrees with distinction from the University of Michigan.

**Defendant Scannon**

54. Defendant Patrick J. Scannon (“Scannon”) has served as a Company director since December 2007. During the Relevant Period, he served on the Audit Committee. According to the 2021 Proxy Statement, as of March 16, 2021, Defendant Scannon beneficially owned 89,144 shares of Company common stock. Given that the price per share of the Company common stock was \$52.16 at the close of trading on March 16, 2021, Defendant Scannon owned approximately \$4.6 million worth of Cassava common stock.

55. For the 2020 Fiscal Year, Defendant Scannon received \$37,962 in compensation from the Company, all in option awards.

56. Upon information and belief, Defendant Scannon is a citizen of California.

57. The 2021 Proxy Statement stated the following about Defendant Scannon:

*Patrick J. Scannon, M.D., Ph.D.* has served as a director since December 2007. Dr. Scannon is one of the founders of XOMA. From 2006 to 2016, Dr. Scannon was Executive Vice President, Chief Biotechnology Officer of XOMA. From 1993 to 2006, Dr. Scannon served as Chief Scientific and Medical Officer of XOMA. Dr. Scannon retired from XOMA and resigned from XOMA's board of directors in 2016. Dr. Scannon received his Ph.D. in organic chemistry from the University of California, Berkeley and his M.D. from the Medical College of Georgia.

### **FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS**

58. By reason of their positions as officers, directors, and/or fiduciaries of Cassava and because of their ability to control the business and corporate affairs of Cassava, the Individual Defendants owed Cassava and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Cassava in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Cassava and its shareholders so as to benefit all shareholders equally.

59. Each director and officer of the Company owes to Cassava and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligations of fair dealing.

60. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Cassava, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

61. To discharge their duties, the officers and directors of Cassava were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

62. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the

affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Cassava, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also the officers and directors of the Company has been ratified by the remaining Individual Defendants who collectively comprised a majority of Cassava's Board at all relevant times.

63. As the senior executive officers and/or directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, including the dissemination of false information regarding the Company's business, prospects, and operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful and accurate information. Further, they had a duty to ensure the Company remained in compliance with all applicable laws.

64. To discharge their duties, the officers and directors of Cassava were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Cassava were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware, Texas, and the United States, and pursuant to Cassava's own Code of Ethics;

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) remain informed as to how Cassava conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Cassava and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Cassava's operations would comply with all applicable laws and Cassava's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(f) exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

65. Each of the Individual Defendants further owed to Cassava and the shareholders the duty of loyalty requiring that each favor Cassava's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

66. At all times relevant hereto, the Individual Defendants were the agents of each other and of Cassava and were at all times acting within the course and scope of such agency.

67. Because of their advisory, executive, managerial, directorial, and controlling positions with Cassava, each of the Individual Defendants had access to adverse, nonpublic information about the Company.

68. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Cassava.

**CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION**

69. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

70. The purpose and effect of the conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (i) facilitate and disguise the Individual Defendants'



violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, gross mismanagement, abuse of control, and violations of the Exchange Act; (ii) conceal adverse information concerning the Company's operations, financial condition, legal compliance, future business prospects, and internal controls; and (iii) artificially inflate the Company's stock price.

71. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company purposefully or recklessly to conceal material facts, fail to correct such misrepresentations, and violate applicable laws. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants who is a director of Cassava was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

72. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in, or substantially assisted in the accomplishment of that wrongdoing, and was or should have been aware of his overall contribution to and furtherance of the wrongdoing.

73. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Cassava, and was at all times acting within the course and scope of such agency.

74.

**CASSAVA’S CODE OF ETHICS AND CORPORATE GOVERNANCE**

***Cassava’s Code of Ethics***

75. Cassava’s Code of Ethics lists some of its purposes which include to:

- Promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Promote full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to the U.S. Securities and Exchange Commission and in other public communications made by the Company;
- Promote compliance with applicable governmental laws, rules and regulations;
- Promote the prompt internal reporting of violations of the Code to appropriate persons of authority within the Company; and
- Promote accountability for adherence to the Code.

76. Moreover, the Company’s Code of Ethics states that:

All directors, officers and employees of the Company will:

1. Act with honesty and integrity, avoiding actual or apparent conflicts between personal and the interests of the Company, including refraining from receiving improper personal benefits as a result of holding a particular position with the Company;

□ □ □

3. Where applicable, provide the U.S. Securities and Exchange Commission (the “Commission”) and the public with complete, fair, accurate, timely and understandable disclosure in periodic reports and other documents filed or submitted to the Commission and in other public communications;

4. Endeavor to comply with applicable laws and regulations of federal, state, local and foreign governments and government agencies having jurisdiction over the Company, and with applicable regulations of private or self-regulatory authorities having jurisdiction over the Company;

5. Act in good faith, responsibly with due care and diligence and without misrepresentation or omission of material facts and strive to maintain independent judgment in the performance and fulfillment of their duties and responsibilities;

6. Promote ethical behavior among subordinates and peers at the Company[.]

77. Finally, with regard to reporting violations of the Code of Ethics itself, the Code of Ethics further provides that: “It is the duty of each director, officer and employee of the Company to report violations of the Code promptly to the attention of the Company’s Chief Executive Officer, Chief Financial Officer or to any member of the Audit Committee of the Board[.]”

***Audit Committee Charter***

78. The Company’s Audit Committee Charters states that among the Audit Committee’s purposes “shall be to make such examinations as are necessary to monitor the Company’s system of internal controls [and] to provide the Company’s Board of Directors with the results of its examinations and recommendations derived therefrom[.]”

79. The Audit Committee Charter also describes the Audit Committee’s responsibilities which include “[r]eviewing on a continuing basis the adequacy of the Company’s system of internal controls” and “[r]eviewing, in conjunction with counsel, any legal matters that could have a significant impact on the Company’s financial statements[.]”

80. The Individual Defendants violated the Code of Ethics by engaging in or permitting the scheme to submit manipulated data to the FDA and to issue materially false and misleading statements to the public, including in the Company’s SEC filings; by facilitating and disguising the Individual Defendants’ violations of law, including breaches of fiduciary duty, waste of corporate assets, unjust enrichment, abuse of control, gross mismanagement, and violations of the Exchange Act; and by failing to report the same. Moreover, the Individual Defendants violated the Code of Ethics by failing to act with honesty and integrity; failing to provide the SEC and public with complete, fair, accurate, timely, and understandable disclosures; failing to comply with

applicable laws and regulations; failing to act in good faith, responsibly with due care and diligence and without misrepresentation or omission of material facts; failing to promote ethical behavior at the Company; and failing to promptly report violations of the Code of Ethics. Further in violation of the Audit Committee Charter, Defendants Gussin, Robertson, and Scannon failed to adequately review the Company's internal controls as well as the Company's SEC filings and FDA submissions

### **THE INDIVIDUAL DEFENDANTS' MISCONDUCT**

#### **Background**

81. Cassava is a biotechnology company that has a product portfolio including simufilam, its lead therapeutic product candidate, and SavaDx, its lead investigational diagnostic product candidate. Simufilam is an Alzheimer's treatment, and SavaDx is a test to detect the presence of Alzheimer's before the appearance of clinical symptoms.

82. One of the Company's much larger competitors, Biogen Inc. ("Biogen"), recently received FDA approval for its Alzheimer's treatment, Aduhelm. However, simufilam represents an appealing potential alternative to Aduhelm, if it were to receive FDA approval, given that it is taken orally, rather than intravenously, and that it is expected to be much cheaper, with Aduhelm costing approximately \$56,000 per patient per year.

83. Cassava is under great pressure to get one or both of its lead product candidates to market, given that, according to the Company's most recent Form 10-Q filed with the SEC on August 4, 2021, Cassava "ha[s] yet to generate any revenues from product sales" and "ha[s] an accumulated deficit of \$183.6 million at June 30, 2021."

84. Immediately prior to the Relevant Period, the Company was finalizing the results of its simufilam Phase 2b clinical trials as it attempted to advance to Phase 3 of the FDA approval process. However, the foundational science the Company used to support its claims of simufilam's

effectiveness was based on a series of papers from two coauthors, Dr. Hoau-Yan Wang of City University of New York and Dr. Lindsay Burns of Cassava. While the clinical trials the Company conducted purportedly showed simufilam's effectiveness, later analysis presented in a citizen's petition to the FDA would show that the data from these trials had been manipulated. According to the citizen petition, no other labs were able to confirm Cassava's research regarding simufilam.

### **False and Misleading Statements Made During the Relevant Period**

#### ***September 14, 2020 Press Release***

85. On September 14, 2020, the Company issued a press release announcing the final results of its Phase 2b clinical study of simufilam. The press release contained false and misleading statements attributed to Defendants Friedmann and Barbier and stated, in relevant part:

Cassava Sciences, Inc. (Nasdaq: SAVA) today announced final results of a Phase 2b study with its lead drug candidate, simufilam, in Alzheimer's disease. In a clinical study funded by the National Institutes of Health (NIH), ***simufilam significantly improved an entire panel of validated biomarkers of disease in patients with Alzheimer's disease. The ability to improve multiple biomarkers from distinct biological pathways with one drug has never been shown before in patients with Alzheimer's disease.*** Study results are expected to be published in a peer-reviewed publication. Simufilam is the first of a new class of drug compounds that bind to a protein called Filamin A.

"Filamin-binding molecules are new to Alzheimer's research and may represent an important advance if these data can be replicated in larger studies," said Jeffrey Cummings, M.D., Sc.D., Founding Director of the Cleveland Clinic Lou Ruvo Center for Brain Health, and Chambers Professor of Brain Science at the University of Nevada, Las Vegas. "I am pleased to see early evidence of disease-modifying effects in patients with this investigational drug. The data appear to represent a step forward toward urgently needed treatments for Alzheimer's disease." In addition, Alzheimer's patients treated with simufilam showed directional improvements in tests of remembering new information, versus patients on placebo. ***Improvements in cognition correlated most strongly with decreases in P-tau181, a biomarker that, when elevated, leads to tangles in the brain. Simufilam decreased brain levels of Ptau-181 by 8-11%, versus placebo.***

In this study, ***Alzheimer's patients treated with 50 mg or 100 mg of simufilam twice-daily for 28 days showed statistically significant ( $p < 0.05$ ) improvements in biomarkers of disease pathology, neurodegeneration and neuroinflammation,***

versus Alzheimer's patients who took placebo. In addition, Alzheimer's patients treated with simufilam showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Sizes 46-17%). ***Cognitive improvements correlated most strongly ( $R^2=0.5$ ) with decreases in P-tau181. The study achieved a 98% response rate, defined as the proportion of study participants taking simufilam who showed improvements in biomarkers.***

***"The clinical data suggest simufilam may be slowing disease progression in Alzheimer's patients," said Nadav Friedmann, PhD/MD, Chief Medical Officer, Cassava Sciences. "This exciting possibility will need to be evaluated in future collaborations with patients, physicians, advisors and others."***

***"Other than a few drugs to help ease the decline, there's really nothing out there to treat people with Alzheimer's," said Remi Barbier, Chairman, President & CEO, Cassava Sciences. "The improvement on multiple biomarkers in this clinical study is a first and offers hope that simufilam has potential to become a transformative treatment for people with Alzheimer's disease."***

(Emphasis added.)

86. The statements from the September 14, 2020 press release, including those made by Defendants Friedmann and Barber, were false and misleading and failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; and (5) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam.

#### ***February 2021 Press Releases***

87. On February 2, 2021, the Company announced the results of an interim analysis from an open-label study of simufilam. The press release contained statements attributed to Defendants Barbier and Friedmann and stated, in relevant part:

***Cassava Sciences, Inc. (Nasdaq: SAVA) today announced results of an interim analysis from an open-label study of simufilam, its lead drug candidate for the***

treatment of Alzheimer's disease. Patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues.

In a clinical study funded by the National Institutes of Health and conducted by Cassava Sciences, six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6. In these same patients, simufilam also improved dementia-related behavior, such as anxiety, delusions and agitation, by 1.3 points on the Neuropsychiatric Inventory, a 29% mean improvement from baseline to month 6.

Alzheimer's is a progressive disease. Over time, a patient's cognition will always worsen. "Experience based on longitudinal studies of ambulatory patients with mild to moderate Alzheimer's disease suggest that scores on ADAS-cog decline by 6 - 12 points per year", according to FDA's Prescription Information sheet for ARICEPT® (donepezil), a drug approved for the treatment of dementia of the Alzheimer's type1.

***"We could not be more pleased with these interim results," said Remi Barbier, President & CEO. "We would have been satisfied to show simufilam stabilizes cognition in patients over 6 months. An improvement in cognition and behavior tells us this drug candidate has potential to provide lasting treatment effects for people living with Alzheimer's disease. It's an exciting development."***

The safety profile of simufilam in the interim analysis was consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

***"Today's data once again suggests simufilam could be a transformative, novel therapeutic," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide a treatment benefit following 6 months of dosing."***

(Emphasis added.)

88. Following this announcement, the price per share of the Company's common stock skyrocketed, from \$22.99 at close on February 1, 2021 to close February 2, 2021 at \$55.44. At close on February 3, 2021 the price per share of the Company's common stock was \$87.95, an increase of approximately 383% from its February 1, 2021 price.

89. On February 8, 2021, Cassava issued another press release announcing "Significant Program Progress and Expected Key Milestones in 2021 for its Clinical Program in Alzheimer's

Disease.” The press release contained a statement attributed to Defendant Barbier and stated, in relevant part:

*“We started 2021 with tremendous momentum, led by results of a 6-month interim analysis from an open-label study of simufilam, our drug candidate for Alzheimer’s disease,” said Remi Barbier, President & CEO. “I believe the rest of the year may be equally exciting.”*

Cassava Sciences’ strategic focus for 2021 is to advance simufilam in a Phase 3 clinical program in Alzheimer’s disease, to expand drug manufacturing capabilities in support of the clinical program, and to continue to lead the Company to deliver the full potential of its product portfolio.

### **Cassava Sciences’ 2021 Scientific and Clinical Outlook**

\* \* \*

Expected progress and key milestones in 2021 across Cassava Sciences’ product portfolio are summarized below.

- ***Based on recent positive clinical results*** and inbound demand from clinical sites, patients, and their caregivers, Cassava Sciences plans to expand the size of the ongoing open-label study of simufilam. The target enrollment will be increased by up to 50 additional patients with mild-to-moderate Alzheimer’s disease, for a total target enrollment of up to 150 patients.
- Cassava Sciences has enrolled approximately 80 patients in the open-label study to date. To accommodate increased enrollment, the Company plans to open new clinical sites across the U.S. and Canada.
- Cassava Sciences expects to announce results of a second interim analysis of the ongoing open-label study when approximately 50 patients complete 12 months of drug treatment. This second interim analysis is expected to include clinical data around long-term safety, cognition and Alzheimer’s-related behavior.
- Cassava Sciences plans to initiate a 6-month, double-blind, randomized, placebo-controlled study in patients with Alzheimer’s disease who complete at least one year of open-label treatment with simufilam. This is a Cognition Maintenance Study (CMS), in which patients who complete one year of open-label treatment will subsequently be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam’s effects on cognition and behavior in patients who continue with drug treatment versus those who discontinue drug treatment. For ethical and other reasons, patients who successfully complete the six-month CMS will have the option to receive open-label simufilam.



- ***Cassava Sciences' clinical and regulatory strategy for simufilam is progressing as planned. In January 2021, the Company concluded a successful End-of-phase 2 (EOP2) meeting with the U.S Food and Drug Administration (FDA). The purpose of the EOP2 was to gain general agreement around a Phase 3 program to treat Alzheimer's disease dementia.***
- As a result of the EOP2 meeting, Cassava Sciences believes its clinical program for simufilam is green-lighted to commence a large, Phase 3 clinical program in patients with Alzheimer's disease, pending official FDA meeting minutes of the EOP2 meeting.
- Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021.
- Cassava Sciences' Phase 3 program for simufilam consists of two large, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease dementia. The Company expects to announce details of its Phase 3 program in Q1 2021, pending official FDA meeting minutes of the EOP2 meeting.
- Cassava Sciences' first Phase 3 study will evaluate disease-modifying effects in Alzheimer's disease patients over 18 months. The goal of this study is to show a slower rate of decline in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.
- Cassava Sciences' second Phase 3 study will evaluate symptomatic improvement in Alzheimer's disease patients over 6 months. The goal of this study is to show improvement in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.
- Cassava Sciences believes its manufacturing strategy is on-track to ensure sufficient drug supply for a Phase 3 program, including both drug substance (i.e., active ingredient) and drug product (i.e., oral tablets).
- Cassava Sciences expects to conclude a long-term, commercial drug supply agreement for simufilam with a contract manufacturing organization. The goal is to ensure the integrity of the drug supply chain on a worldwide basis, in compliance with FDA standards.
- Cassava Sciences expects to initiate a validation study with SavaDx, its investigational diagnostic for the detection of Alzheimer's disease.
- Cassava Sciences is in discussions with scientific and clinical advisors about potentially expanding therapeutic indications for simufilam outside of Alzheimer's disease, but still within neurodegenerative conditions.

### Other Expected Milestones and Announcements for 2021

- *Cassava Sciences expects to announce publication of Phase 2b results in a peer-reviewed technical journal.*
- Net cash use for full-year 2021 is expected to be in the range of \$20 to \$25 million, depending on enrollment rates in its clinical programs and other factors. On December 31, 2020, unaudited cash and cash equivalents were approximately \$93 million.

(Italicized emphasis added.)

90. On February 10, 2021, Cassava announced an offering of its common stock priced at \$49 per share for a total of \$200 million. On February 12, 2021, the Company completed the offering.

91. On February 22, 2021, the Company issued a press release announcing a “Positive End-of-Phase 2 Meeting with FDA and Outlin[ing a] Pivotal Phase 3 Program for Simufilam in Alzheimer’s Disease.” The press release contained statements from Defendants Barbier and Kupiec and stated, in relevant part:

**- Two Upcoming Phase 3 Studies and a Previously Completed Phase 2 Program Support a New Drug Application Filing for Simufilam in Alzheimer’s disease –**

**- Agreement Reached to Use ADAS-Cog as Co-Primary Efficacy Endpoint –**

**- Pivotal Phase 3 Program Remains On-track to be Initiated 2nd Half 2021 –**

... Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company developing product candidates for Alzheimer’s disease, *today announced the successful completion of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) for simufilam*, its lead drug candidate for the treatment of Alzheimer’s disease. *Official EOP2 meeting minutes indicate FDA and Cassava Sciences agree on key elements of a pivotal Phase 3 clinical program in support of a New Drug Application (NDA) filing for simufilam* in Alzheimer’s disease. Agreements reached during the EOP2 meeting show a clear path forward for advancing simufilam into Phase 3 studies in the second half of 2021.

*“For over 10 years we’ve been doing basic research and early drug development with simufilam,” said Remi Barbier, President & CEO. “We are excited to finally*

advance simufilam into pivotal Phase 3 clinical studies in people with Alzheimer's disease. *We believe the underlying science is solid, the drug appears safe and the clinical roadmap makes sense.* We've crossed the Rubicon."

*"We appreciate the valuable guidance and flexibility FDA has provided," added Jim Kupiec, MD, Cassava Sciences' Chief Clinical Development Officer. "We look forward to continuing a collaborative dialogue throughout the pivotal Phase 3 clinical development program."*

Simufilam is a novel drug, discovered at Cassava Sciences, that targets both neuroinflammation and neurodegeneration. *The EOP2 meeting discussion was supported by years of scientific and clinical data, including positive results from a previously completed Phase 2 clinical program with simufilam in Alzheimer's disease. In a double-blind, randomized, placebo-controlled Phase 2b study, simufilam demonstrated robust effects on primary and secondary outcome measures, with no safety issues. Recently, the Company announced that simufilam improved cognition in subjects with Alzheimer's disease in a 6-month interim analysis of an open-label study, with no safety issues.*

The EOP2 meeting took place mid-January. FDA attendees included Robert Temple, MD, Deputy Center Director for Clinical Science and Senior Advisor in the Office of New Drugs; Billy Dunn, MD, Director, Office of Neuroscience; Eric Bastings, MD, Director, Division of Neurology, and others.

Official meeting minutes confirm that Cassava Sciences and FDA are aligned on key elements of a Phase 3 clinical program for simufilam. *FDA has agreed that the completed Phase 2 program, together with an upcoming and well-defined Phase 3 clinical program, are sufficient to show evidence of clinical efficacy for simufilam in Alzheimer's disease.* There is also agreement that the use of separate clinical scales to assess cognition (ADAS-cog1) and function (ADCS-ADL2) are appropriate co-primary endpoints of efficacy. A clinical scale that combines cognition and function, such as iADRS3, is a secondary efficacy endpoint.

(Italicized emphasis added.)

92. However, the February 2, 2021 press release, February 8, 2021 press release, and February 22, 2021 press release were false and misleading and failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with

simufilam was manipulated to show simufilam was effective; and (5) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam.

***March 2021 Press Releases***

93. On March 9, 2021, the Company announced that “it ha[d] entered into a drug supply agreement with Evonik Industries AG for simufilam. Under the agreement, Evonik will supply Cassava Sciences with large-scale, clinical-grade quantities of simufilam, a drug candidate for the treatment of Alzheimer’s disease.”

94. On March 23, 2021, the Company issued a press release touting its “Full-year 2020 Financial Results and Business Highlights.” The press release contained the following statements from Defendants Barbier and Schoen, in relevant part:

“In Q1 2021 we announced that our lead drug candidate, simufilam, improved cognition scores in 50 patients with Alzheimer’s disease who completed at least 6 months of open-label treatment,” ***said Remi Barbier***, President & CEO. “In mid-2021, we look forward to announcing cognition scores in patients who’ll have completed at least 12 months of open-label treatment with simufilam. To our knowledge, no drug has stabilized, much less improved, cognition scores over 12 months in patients with Alzheimer’s disease. For this reason, I feel there is a sense of anticipation around the upcoming release of 12-month clinical data from our open-label study, as well as our plans to conduct a pivotal Phase 3 program with simufilam in the second half of 2021. ***With solid science, the right people in place, cash in the bank and a clinical roadmap that makes sense, I think Cassava Sciences is positioned to becoming a premier organization to serve patients with Alzheimer’s disease.***”

“We have approximately \$280 million in cash on our balance sheet, against expected cash use of approximately \$20 to \$25 million in 2021,” said Eric Schoen, Chief Financial Officer. “We believe our cash levels support a pivotal Phase 3 clinical program of simufilam in Alzheimer’s disease.”

95. However, contrary to Defendant Barbier’s assertion that the Company had “solid science,” Defendant Barbier and the March 23, 2021 press release failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam’s efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was

manipulated; (3) the Company's experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; and (5) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam.

***March 23, 2021 Form 10-K***

96. Also on March 23, 2021, Cassava filed its annual report for the 2020 Fiscal Year on Form 10-K with the SEC (the "2020 10-K"). The 2020 10-K was signed by Defendants Barbier, Schoen, Friedmann, Gussin, O'Donnell, Robertson, and Scannon and contained certifications, signed by Defendants Barbier and Schoen, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Exchange Act and the Sarbanes-Oxley Act of 2002 ("SOX") attesting to the accuracy of the financial statements contained in the 2020 10-K, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

97. The 2020 10-K also contained this general risk warning:

***Since 2017, we have concentrated a substantial portion of our research and development efforts on the treatment and detection of Alzheimer's disease, an area of research that has seen significant failure rates. Further, our product candidates are based on new scientific approaches and novel technology, which makes it difficult to predict the time and cost of product candidate development and likelihood of success.***

Since 2017, we have concentrated a substantial portion of our research and development efforts on experimental methods for the treatment and detection of Alzheimer's disease. Prior efforts by biopharmaceutical companies to develop new treatments for Alzheimer's disease have seen very limited clinical success. No new treatments have been approved for Alzheimer's disease since 2003, and since that time, while many large clinical studies have been completed, no drug candidate has shown clear evidence of clinical efficacy in large, Phase 3 clinical studies. FDA-approved drugs for Alzheimer's disease only address symptoms, and there are no FDA-approved disease modifying therapeutics available for patients with Alzheimer's disease. Notwithstanding these substantial challenges to date, we seek to improve brain health by addressing the neurodegeneration and

neuroinflammation components of Alzheimer's disease. Our lead drug candidate for Alzheimer's disease is based on a new approach of stabilizing – but not removing – a critical protein in the brain. We cannot be certain that our novel technologies will lead to an approvable or marketable product. In addition, because FDA has limited comparators to evaluate our lead drug candidate, we could experience a longer than expected regulatory review process and increased development costs.

98. Moreover, the 2020 10-K contained this general risk warning:

***Our clinical studies may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization.***

\* \* \*

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical studies, and results of early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. The results of clinical studies in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen, and other clinical study protocols and the rate of dropout among clinical study participants. Open-label extension studies may also extend the timing and cost of a clinical study substantially. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical studies. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier studies. This is particularly true in neurodegenerative diseases, where failure rates historically have been higher than in many other disease areas. Most product candidates that begin clinical studies are never approved by regulatory authorities for commercialization.

\* \* \*

In addition, even if such clinical studies are successfully completed, we cannot guarantee that FDA or foreign regulatory authorities will interpret the results as we do, and more studies could be required before we submit our product candidates for approval. To the extent that the results of the studies are not satisfactory to FDA or foreign regulatory authorities for support of a marketing application, we may be

required to expend significant resources, which may not be available to us, to conduct additional studies in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit its commercial potential.

99. Finally, the 2020 10-K contained this statement regarding the Company's internal controls:

*Evaluation of disclosure controls and procedures.*

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. ***Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission, or SEC, rules and forms and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.***

*Management's annual report on internal control over financial reporting.* Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2020. Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework (2013 Framework).

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in



- (3) accordance with authorizations of our management and board of directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

***Based on the COSO criteria, we believe our internal control over financial reporting as of December 31, 2020 was effective.***

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*Changes in internal control over financial reporting.*

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(Bolded emphasis added.)

100. Despite the generalized risk warnings concerning new drug research and clinical trials, the 2020 10-K failed to disclose or discuss the specific risks the Company was facing due to its use of overstated and manipulated clinical trial data. Thus, the above statements from the 2020 10-K was false and misleading and failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; (5) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (6) the Company failed to maintain internal controls.



***March 31, 2021 Proxy Statement***

101. On March 31, 2021, Cassava filed the 2021 Proxy Statement with the SEC. Defendants Barbier, Friedmann, Gussin, O'Donnell, Robertson, and Scannon solicited the 2021 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.<sup>1</sup>

102. The 2021 Proxy Statement called for Company shareholders to, *inter alia*: (1) reelect Defendants Barbier, Robertson, and Scannon to the Board; (2) approve an amendment to the Company's 2018 Omnibus Incentive Plan (the "2018 Plan") to add an additional 4 million shares to the 2018 Plan for issuance to Company employees, directors, and consultants; (3) ratify Ernst & Young LLP as the Company's independent auditor for the fiscal year ending December 31, 2021; and (4) approve, by a nonbinding advisory vote, the 2020 executive compensation for Defendants Barbier, Friedmann, and Schoen.

103. The 2021 Proxy Statement stated the following regarding the Board's risk oversight functions:

The Board of Directors maintains a structure with the Chief Executive Officer of the Company holding the position as Chairman of the Board of Directors, and with an Audit Committee and Compensation Committee for oversight of specific areas of responsibility, discussed further below. The Company does not have a lead independent director. ***The Company believes that this structure is appropriate and allows for efficient and effective oversight***, given the Company's relatively small size (both in terms of number of employees and in scope of operational activities directly conducted by the Company), its corporate strategy (including the use of outsourcing for certain activities) and its focus on drug and diagnostic research and development. ***The Chairman, President and Chief Executive Officer, the Committees of the Board of Directors and, as needed, other executive officers and employees of the Company provide the Board of Directors with information***

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<sup>1</sup> Plaintiff's allegations with respect to the misleading statements in the 2021 Proxy Statement are based solely on negligence; they are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants, and they do not allege, and do not sound in, fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these allegations and related claims.

***regarding the Company's risks. The Board of Directors, or the Committee with special responsibility for oversight of the area implicated by the highlighted risks, then uses this information to perform its oversight role and inform its decision making with respect to such areas of risk.***

(Emphasis added.)

104. The 2021 Proxy Statement contained the following description of the Board committees:

***The Board of Directors has a standing Audit Committee that oversees the Company's accounting and financial reporting processes and audits of the Company's financial statements.*** The Company also has a standing Compensation Committee. The Board of Directors does not have a lead director or a standing Nominating Committee. Mr. Barbier is the Chairman of the Board of Directors, President and Chief Executive Officer of the Company.

The Audit Committee consists of directors Dr. Gussin, Mr. Robertson and Dr. Scannon. . . . The Board of Directors of the Company has determined that these individuals are independent as defined under the Nasdaq Stock Market LLC listing standards as well as the SEC rules. The Board of Directors has also determined that Mr. Robertson is an "audit committee financial expert" as defined in the SEC rules. The Audit Committee operates under a written charter adopted by the Board of Directors. The Company maintains a copy of the Audit Committee charter on its website: [www.cassavasciences.com](http://www.cassavasciences.com). The Audit Committee reviews the Company's internal accounting procedures, consults with and reviews the services provided by the Company's independent registered public accounting firm and makes recommendations to the Board of Directors regarding the selection of the independent registered public accounting firm. The Audit Committee held four meetings during fiscal year 2020.

The Compensation Committee consists of directors Dr. Gussin and Mr. Robertson. The Board of Directors of the Company has determined that these individuals are independent as defined under the Nasdaq Stock Market LLC listing standards. ***The Compensation Committee reviews and recommends to the Board of Directors the salaries, incentive compensation and benefits of the Company's officers and administers the Company's stock plans and employee benefit plans.*** Refer to the section entitled "Compensation Discussion and Analysis" for more information about the Company's Compensation Committee and its processes and procedures. The Compensation Committee operates under a written charter adopted by the Board of Directors. The Company maintains a copy of the Compensation Committee charter on its website: [www.cassavasciences.com](http://www.cassavasciences.com). The Compensation Committee held three meetings during fiscal year 2020.

(Emphasis added.)

105. The 2021 Proxy Statement also listed certain responsibilities of the Audit Committee, that included, “[a]ssist[ing] the Board of Directors of the Company in oversight and monitoring” and overseeing “the adequacy and effectiveness of the Company’s systems of internal accounting and financial controls[.]”

106. The 2021 Proxy Statement noted that of “the 1,000,000 shares of Common Stock originally authorized under the 2018 Plan, after all award grants made by the Compensation Committee of our Board of Directors (the “Compensation Committee”), 242,188 shares remained available for grant as of March 16, 2021.”

107. The 2021 Proxy Statement was materially misleading because it failed to disclose that: (1) contrary to the 2021 Proxy Statement’s descriptions of the Board’s risk oversight function and the Audit Committee’s responsibilities, the Board and its committees were not adequately exercising these functions, were causing or permitting the Company to submit manipulated data to the FDA and to issue false and misleading statements to the investing public, and thus the Individual Defendants on the Board were breaching their fiduciary duties; and (2) the Individual Defendants on the Board who were breaching their fiduciary duties were improperly interested in increasing their unjust compensation by seeking shareholder approval of the amendment to the 2018 Plan, which the Individual Defendants serving on the Compensation Committee were improperly administering by rewarding misconduct.

108. The 2021 Proxy Statement also failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam’s efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company’s experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to

show simufilam was effective; (5) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (6) the Company failed to maintain internal controls

109. As a result of the material misstatements and omissions contained in the 2021 Proxy Statement, Company shareholders reelected Defendants Barbier, Robertson, and Scannon to the Board, allowing them to continue breaching their fiduciary duties to Cassava; ratified Ernst & Young LLP as independent auditor, and approved, on a nonbinding advisory basis, the 2020 compensation Defendants Barbier, Friedmann, and Schoen. Company shareholders did not approve the amendment to the 2018 Plan.

***April 21, 2021 Press Release***

110. On April 21, 2021, Cassava issued a press release announcing its results for the fiscal quarter ended March 31, 2021. The press release contained a statement from Defendant Barbier and stated in relevant part:

- 9 Month Interim Analysis of Open-label Study to be Presented at a Major Scientific Conference in July 2021 as an Oral Presentation –**
- Initiation of Pivotal Phase 3 Program Remains On-track for 2<sup>nd</sup> Half 2021 –**
- Initiation of Cognition Maintenance Study On-track for June 2021 –**
- Cash and cash equivalents were \$282.2 million at March 31, 2021 –**

... Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the first quarter ended March 31, 2021 and guidance regarding the release of new clinical data with simufilam. Simufilam is the Company's lead drug candidate to treat Alzheimer's disease.

***“Alzheimer's is a progressive disease, so a patient's cognition is expected to worsen over time,” said Remi Barbier, President & CEO. “Patients' cognition scores actually improved following 6 months of open-label treatment with simufilam. Showing similar drug effects following 9 months of open-label treatment would be remarkable, yet consistent with simufilam's mechanism of***

***action. Eventually, we'd like this drug candidate to benefit cognition for a year or longer."***

In July 2021, Cassava Sciences plans to announce results of a pre-specified interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 9 months of open-label drug treatment. The Company will present these data July 26 - 29<sup>th</sup> at the 2021 Alzheimer's Association International Conference (AAIC). AAIC's scientific committee has invited the Company's scientists to present the dataset as an oral presentation.

### **About the Open-label Study with Simufilam**

In March 2020, Cassava Sciences initiated a long-term, open-label study to evaluate simufilam in patients with Alzheimer's disease. This study is funded by a research grant award from the National Institutes of Health (NIH). The open-label study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice-daily for 12 months or longer in patients with Alzheimer's disease. Another study objective is to measure changes in cognition on ADAS-Cog, a standard test of cognition in Alzheimer's disease. The study's clinical protocol has pre-specified cognition measurements at 6, 9 and 12 months.

The study's target enrollment is approximately 150 subjects with mild-to-moderate Alzheimer's disease (recently increased by 50 subjects). One-hundred subjects have enrolled in this study across multiple clinical sites in the U.S. and Canada.

On February 2, 2021, Cassava Sciences announced positive results of a first interim analysis that summarizes clinical data on the first 50 subjects to complete 6 months of open-label treatment. Patients' cognition scores improved from baseline following 6 months of simufilam treatment, with no safety issues. Six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6.

In September 2021, Cassava Sciences plans to announce results of an interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 12 months of open-label drug treatment.

### **About the Cognition Maintenance Study (CMS)**

In June 2021, Cassava Sciences plans to initiate a double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease. Patients who have completed at least one year of open-label treatment with simufilam qualify to enroll in the *Cognition Maintenance Study* (CMS). Study subjects in the CMS will be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition in Alzheimer's patients who continue with drug treatment versus patients who discontinue drug treatment.

(Italicized emphasis added.)

111. The April 21, 2021 press release was false and misleading and failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; and (4) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam.

***June 21, 2021 Press Release***

112. On June 21, 2021, the Company issued a press release providing a "Mid-Year Corporate Update[.]" The press release contained a statement from Defendant Barbier and stated, in relevant part:

- **Open-label Study Completes Patient Enrollment**
- **Cognition Maintenance Study Initiated May 2020, now 30% Enrolled**
- **6-month Biomarker Data to be Presented at AAIC Conference in July**
- **9-month Safety & Cognition Data to be Presented at AAIC Conference**
- **Clinical Results with SavaDx to be Presented at AAIC Conference**
- **Phase 3 Program Initiation Remains On-track for 2<sup>nd</sup> Half 2021**

...Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today announced a mid-year update that highlights clinical development progress and provides guidance on upcoming data releases for simufilam and SavaDx. Simufilam is Cassava Sciences' lead drug candidate to treat Alzheimer's disease; SavaDx is an investigational diagnostic candidate to detect Alzheimer's with a simple blood test.

***"Patients with Alzheimer's want clear and present evidence of drug efficacy," said Remi Barbier, President & CEO. "The recent regulatory approval of a new drug for Alzheimer's was a bit of a donnybrook over this very topic. Our clinical strategy with simufilam is to show real-world safety and efficacy by conducting both, randomized controlled trials, and an on-going open-label study. Ideally, biomarker and cognition data from our studies converge and result in health benefits for patients."***

Clinical progress across Cassava Sciences' product portfolio is summarized below.

### **Update on Open-label Study with Simufilam**

□ □ □

The open-label study has completed its target enrollment of 150 subjects. By physician and patient request, clinical sites may continue to enroll additional subjects up through the initiation of the Company's Phase 3 pivotal program of simufilam.

### **Guidance on Clinical Data Release**

Cassava Sciences plans to announce results of an interim analysis on safety and cognition for the first 50 subjects to complete 9 months of open-label drug treatment. These cognition data will be presented at the 2021 Alzheimer's Association International Conference (AAIC) in Denver, CO, the week of July 26-30<sup>th</sup>. The scientific committee of AAIC has invited the Company's scientists to present these data as an oral presentation.

Cassava Sciences will also present at AAIC biomarker data from the open-label study, including:

- Biomarkers of Alzheimer's disease: amyloid beta42, total tau, P-tau181.
- Biomarkers of neurodegeneration: neurogranin, neurofilament light chain (NfL).
- Biomarkers of neuroinflammation: YKL-40, sTREM2 and HMGB1.

*Biomarker data were analyzed from cerebrospinal fluid (CSF) collected from twenty-five study subjects who underwent a small volume lumbar puncture at baseline and again after completing 6 months of open-label drug treatment.*

□ □ □

### **Update on the Phase 3 Clinical Program**

*Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021.* A clinical research organization (CRO) has been selected and will be publicly announced shortly. Large-scale, cGMP drug production capabilities are in-place to support the Phase 3 clinical program.

(Italicized emphasis added; some original emphasis removed.)

113. The June 21, 2021 press release was false and misleading and failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam's efficacy was



overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; and (4) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam.

***July 2021 Press Releases***

114. On July 26, 2021, Cassava issued a press release titled “Cassava Sciences Announces Positive Data with SavaDx from a Randomized Controlled Phase 2b Study of Simufilam[.]” The press release contained a statement from Defendant

- **SavaDx Detected Significant Changes in Plasma Levels of Altered Filamin A in Patients with Alzheimer’s Disease Before and After Simufilam Treatment**
- **Simufilam 100 mg and 50 mg Reduced Plasma Levels of Altered Filamin A in Alzheimer’s Patients 48% (p=0.003) and 44% (p=0.02) Respectively**
- **Plasma Results with SavaDx Track Plasma Results with p-Tau181**
- **Plasma Data Provide Evidence of Target Engagement**
- **Poster Presentation at AAIC Today**

... Cassava Sciences, Inc. (Nasdaq: SAVA) today announced positive clinical data with SavaDx, an investigational diagnostic/biomarker to detect Alzheimer’s disease with a simple blood test. SavaDx was used to measure plasma levels of altered filamin A before and after simufilam treatment in patients with Alzheimer’s disease. In this Phase 2b randomized, controlled trial sponsored by the National Institutes of Health (NIH), simufilam significantly reduced plasma levels of altered filamin A in Alzheimer’s patients treated for 28 days. Plasma levels of p-tau181 also dropped significantly in these same patients.

Simufilam 100 mg and 50 mg reduced plasma levels of altered filamin A by 48% (p=0.003) and 44% (p=0.02) respectively, versus placebo. Additionally, simufilam 100 mg and 50 mg reduced plasma levels of p-tau181 by 17% (p=0.01) and 15% (p=0.02) respectively, versus placebo. Plasma p-tau181 is a biomarker that is known to be elevated in Alzheimer’s disease.



*“We believe altered filamin A is a major culprit in Alzheimer’s disease,” said Remi Barbier, President & CEO. “Before simufilem treatment, SavaDx detected high plasma levels of altered filamin A in patients. After simufilem treatment, levels dropped significantly. We believe these data provide clear evidence that simufilem binds to and engages its intended target to produce treatment effects.”*

Treatment effects on CSF biomarkers for this Phase 2b study have been previously reported.

(Italicized emphasis added.)

115. On July 29, 2021, Cassava issued a press release, one of two released that day, titled, “Cassava Sciences Announces Positive Biomarker Data with Simufilem in Alzheimer’s Disease[.]” The press release contained a statement from Defendant Barbier, and stated in relevant part:

- **Simufilem Significantly Improved Biomarkers in Alzheimer’s Patients Treated for 6 Months**
- **Robust Improvements Seen in All Measured Biomarkers of Disease, Neurodegeneration and Neuroinflammation ( $p < 0.00001$ )**
- **Biomarker Improvements Track with Cognitive Improvements**
- **Oral Presentation at AAIC Today**

... Cassava Sciences, Inc. (Nasdaq: SAVA) *today announced positive biomarker data from an open-label study of simufilem*, the Company’s investigational drug for the treatment of Alzheimer’s disease.

*In a clinical study funded by the National Institutes of Health (NIH), simufilem significantly improved all measured biomarkers in patients with Alzheimer’s disease following 6 months of open-label treatment. Biomarkers are objective biological data. There are no placebo effects.*

Cerebrospinal fluid (CSF) biomarkers of disease pathology, t-tau and p-tau181, decreased 38% and 18%, respectively (both  $p < 0.00001$ ). CSF biomarkers of neurodegeneration, neurogranin and Nfl, decreased 72% and 55%, respectively (both  $p < 0.00001$ ). CSF biomarkers of neuroinflammation, sTREM2 and YKL-40, decreased 65% and 44% (both  $p < 0.00001$ ). CSF biomarker data were collected

from 25 patients with mild-to-moderate Alzheimer's disease who completed 6 months of simufilam treatment in an on-going open-label study.

***“Six months of simufilam treatment robustly improved brain biomarkers,” said Remi Barbier, President & CEO. “In this same study simufilam also improved cognition. These data suggest simufilam has potential to provide durable treatment effects for people living with Alzheimer’s.”***

(Italicized emphasis added.)

116. The July 26, 2021 press release and the July 29, 2021 press release titled “Cassava Sciences Announces Positive Biomarker Data with Simufilam in Alzheimer’s Disease[.]” were false and misleading and failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam’s efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company’s experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; and (5) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam.

**The Truth Begins Emerging but the False and Misleading Statements Continue**

***Second July 29, 2021 Press Release***

117. Also on July 29, 2021, the Company issued a different press release titled “Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer’s Disease[.]” While the title, and the press release itself, framed the newly-released cognition data as being a positive development for the Company, observers recognized that the simufilam data presented showed that Cassava’s product was no more effective than Biogen’s product, Aduhelm.

118. Therefore, on this news, the price per share of the Company's common stock fell dramatically, from \$135.30 at close on July 28, 2021, to \$103.35 at close on July 29, 2021, to \$69.53 at close on July 20, 2021. This was a two-day decline of \$65.77, or approximately 48.6%.

119. Despite this revelation, the Individual Defendants continued to make or cause the Company to make false and misleading statements preventing the full truth from becoming known and keeping the Company's stock price artificially inflated.

120. In the very same July 29, 2021 press release titled, "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease[.]" the Company, and Defendants Barbier and Friedmann, still touted the data being presented as positive. The press release stated, in relevant part:

- **Simufilam Significantly Improves Cognition in Patients with Alzheimer's in Interim Analysis of Open-label Study at 9 Months**
- **Cognition Improved 3.0 Points on ADAS-Cog at 9 Months ( $p < 0.001$ )**
- **Cognitive Improvements Track with Biomarker Improvements**
- **No Behavior Disorders in Over 50% of Patients**
- **No Safety Issues**
- **Improvements in Cognition, Biomarkers and Behavior Suggest Highly Encouraging Treatment Effects**
- **Oral Presentation at AAIC Today**

... Cassava Sciences, Inc. (Nasdaq: SAVA) *announced positive clinical data today* from an interim analysis of an open-label study with simufilam, the Company's investigational drug for the treatment of Alzheimer's disease.

In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved cognition in Alzheimer's patients, with no safety issues. Simufilam improved cognition scores 3.0 points on ADAS-Cog11, an 18% mean improvement, baseline to month 9 ( $p < 0.001$ ). This interim analysis summarizes clinical data from the first 50 patients with mild-to-moderate Alzheimer's disease who completed 9 months of open-label simufilam treatment.

Cassava Sciences believes today's data is the first report of significant cognitive improvements at 9 months that also track with robust improvements in biomarkers in patients with Alzheimer's.

***"We are very pleased with the overall consistency of data," said Remi Barbier, President & CEO. "Simufilam improved cognition, biomarkers and behavior, a triple-win for study participants. These clinical data combined with a clean safety profile and easy oral administration suggest highly encouraging and durable treatment effects for people living with Alzheimer's disease."***

Alzheimer's is a progressive disease. Cognition will always decline over time. In patients with mild-to-moderate Alzheimer's disease, cognition scores decline over 4 points on ADAS-Cog over 9 months with over 90% certainty, as reported by the science literature<sup>1</sup>.

Simufilam improved ADAS-Cog scores in 66% of patients at 9 months. An additional 22% of patients declined less than reported in the science literature at 9 months. Cognition outcomes suggest simufilam's treatment effects were broad-based.

Alzheimer's is often accompanied by behaviors disorders, such as anxiety, agitation or delusions. These may become more frequent as disease progresses. Simufilam reduced dementia-related behavior at 9 months on the Neuropsychiatric Inventory (NPI), a clinical tool widely used to measure changes in dementia-related behavior.

- At baseline, 34% of study subjects had no neuropsychiatric symptoms.
- At month 6, 38% of study subjects had no neuropsychiatric symptoms.
- At month 9, over 50% of study subjects had no neuropsychiatric symptoms.

The safety profile of simufilam in the interim analysis is consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

***"Today's data with simufilam suggests disease modification," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide transformative treatment benefits following 9 months of dosing."***

In February 2021, Cassava Sciences reported that simufilam improved cognition scores by 1.6 points on ADAS-Cog11, a 10% improvement, following six months of open-label treatment.

(Italicized emphasis added.)

***August 24, 2021 Press Release***

121. On August 24, 2021, the Company issued a press release titled, “Cassava Sciences Announces Agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 Studies of Simufilam for the Treatment of Alzheimer’s Disease[.]” The press release contained a statement by Defendant Barbier and stated, in relevant part:

. . . Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer’s disease, announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for both of its pivotal Phase 3 studies of oral simufilam for the treatment of patients with Alzheimer’s disease.

These SPA agreements document that FDA has reviewed and agreed upon the key design features of Cassava Sciences’ Phase 3 study protocols of simufilam for the treatment of patients with Alzheimer’s disease.

***“I believe these SPAs mark a meaningful and encouraging milestone for Cassava Sciences,” said Remi Barbier, President & CEO. “The SPAs underscore our alignment with FDA on key scientific, clinical and regulatory requirements of our Phase 3 program of simufilam in Alzheimer’s disease.”***

Cassava Sciences also reaffirmed prior guidance to advance simufilam into a Phase 3 pivotal program in Alzheimer’s disease in Fall 2021.

(Emphasis added.)

122. The statements in the July 29, 2021 press release titled, “Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer’s Disease[.]” and the August 24, 2021 press release were false and misleading and failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam’s efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company’s experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; and (5) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam.

***August 24, 2021 Citizen Petition***

123. On August 24, 2021, after the market had closed, a citizen petition submitted to the FDA and challenging the accuracy and integrity of clinical data supporting simufilam became publicly available. The petition, dated August 18, 2021, requested that the FDA “halt the current clinical studies of Simufilam . . . pending audits of (1) the publications relied on by Cassava in support of its scientific claims concerning Simufilam; (2) the IND [Investigation New Drug] application for Simufilam’s use in Alzheimer’s Disease; and (3) all clinical biomarker studies of Simufilam in Alzheimer’s Disease.”

124. The petition’s “Statement of Grounds,” section stated as follows in support of its request:

Petitioner has enclosed with this Petition (and incorporates herein) a detailed technical report presenting ***multiple reasons to question the quality and integrity of the research supporting Cassava’s claims about Simufilam’s use for Alzheimer’s Disease.*** In sum, that report explains:

(1) ***All of the foundational science supporting Cassava’s claims about Simufilam’s use for Alzheimer’s Disease comes from a series of papers with two common co-authors (Dr. Hoau-Yan-Wang at City University of New York and Dr. Lindsay Burns of Cassava).*** The studies of Drs. Wang and Burns were used by Cassava to obtain NIH grants and to open an Investigational New Drug (IND) application to study Simufilam. They form the foundation for the current clinical trials of Simufilam.

(2) ***No other lab has confirmed Cassava’s research connecting Filamin A to Alzheimer’s Disease, nor has any other lab confirmed that Simufilam binds or modifies Filamin A or has effects in Alzheimer’s Disease models.***

(3) Close review of the data and analyses in the foundational research papers and Cassava’s recent publications of clinical trial analyses presents primary areas of concern:

a. The underlying papers of Drs. Wang and Burns involve extensive use of Western blot analyses to support their claims connecting Simufilam to Alzheimer’s. ***Detailed analysis of the western blots in the published journal articles shows a series of anomalies that are suggestive of systematic data manipulation and misrepresentation.***

- b. Some of the foundational studies published by ***Drs. Wang and Burns make claims about Simufilam's effects in experiments conducted on postmortem human brain tissue. The methodology allegedly used in those experiments defies logic, and the data presented again have the hallmarks of manipulation.***
- c. Cassava's presentation of clinical biomarker data from the Phase 2b trials raises questions about the validity of the data. ***The CSF samples in this study were first analyzed by an outside lab, which found that Simufilam was ineffective*** in improving the primary biomarkers end point and high variability in other biomarkers. ***But Cassava had these samples analyzed again and this time reported that Simufilam rapidly and robustly improved a wide array of biomarkers. Cassava has not fully published the data from this reanalysis, but a presentation poster that it published on July 26, 2021, which appears to describe aspects of that work, shows signs of data anomalies or manipulation.***
- (4) ***Six further aspects*** of the research by Drs. Wang and Burns are incompatible with scientific norms, and these claims ***raise further suspicions.***
- a. Remarkably High Affinity Binding Between PTI-125 and Filamin A.
  - b. Remarkably High Affinity Binding Between Naloxone and Filamin A
  - c. Isoelectric Focusing Experiments in Multiple Papers Indicate 100% of Filamin in Altered Conformation in Alzheimer's Disease and largely Restored to Correct Conformation by PTI125.
  - d. Novel Blood Diagnostic SavaDx Represents Plasma Filamin A Level
  - e. PTI-125/Simufilam Improves Memory in a Mouse Model of Alzheimer's Disease.
  - f. PTI-125/Simufilam Blocks the Interaction Between B-amyloid and  $\alpha 7$  – Nicotinic Acetylcholine Receptors.

(Emphasis added.)

125. The forty-two page “Statement of Concern Regarding the Accuracy and Integrity of Clinical and Preclinical Data Supporting the Ongoing Clinical Evaluation of Compound PTI-125, Also Known As Simufilam[,]” filed as an attachment to the petition and incorporated into it, further noted in its introduction, in relevant part:



In this document, *three primary concerns are raised*:

- The validity of clinical biomarker data: Biomarker analysis from patients treated with simufilam in Cassava’s double-blind study forms a primary basis of Cassava’s claim that simufilam engages its target in the central nervous systems, but *there are concerns about the integrity of this data. The CSF samples in this study were analyzed by an outside lab, which found that simufilam was ineffective* in improving the primary biomarker end point and showed high variability in other biomarkers. *However, Cassava Science had these samples bioanalyzed again and the data were finalized in an academic lab, which apparently refers to Dr. Wang. This re-analysis showed that simufilam rapidly and robustly improved a wide array of CSF biomarkers. Whereas Cassava has not fully published this reanalysis, Cassava’s 26 July 2021 poster presumably describing aspects of that work shows signs of data manipulation.*
- The integrity of western blot analyses: Western blotting was extensively used by Drs. Wang and Burns over the past 15 years to support their foundational scientific claims and underscores their SavaDx clinical plasma biomarker. *Detailed analysis of the western blots in the published journal articles from Drs. Wang and Burns shows a series of anomalies. The extent of these anomalies forms a 15-year pattern that strongly suggests systematic data manipulation and misrepresentation.*
- The integrity of analyses involving human brain tissue: Simufilam is reported to bind to its target and modify a range of downstream molecules in experiments conducted on post-mortem human brain tissue from subjects with Alzheimer’s disease and neurological controls. *The same human brain specimens are used across the studies from 2008-2017, so the results are premised on human neurons remaining viable up to 13 hours after death, then being successfully reanimated after nearly 10 years in frozen archival without any advanced cryopreservation techniques. The complex, multi-step cellular processes the authors claim to observe in tissue that has been dead for a decade are contrary to a basic understanding of neurobiology. As with the western blot data, there are anomalies in the presentation of the data which again strongly suggests manipulation.*

(Emphasis added.)

126. The citizen petition concluded by stating that: “the extensive evidence set forth in the enclosed report, which presents grave concerns about the quality and integrity of the scientific data supporting Cassava’s claims for Simufilam’s efficacy, provides compelling grounds for



pausing the ongoing clinical trials until the FDA can conduct and complete a rigorous audit of Cassava's research."

***August 25, 2021 Company Response***

127. The next morning, before the market opened, Cassava issued a response to the citizen petition. The Company's response stated as follows, in relevant part:

***Fiction: Biomarker data is generated by Cassava Sciences or its science collaborators and therefore are falsified.***

***Fact: Cassava Sciences' plasma p-tau data from Alzheimer's patients was generated by Quanterix Corp., an independent company, and presented at the recent Alzheimer's Association International Conference.***

***Fiction:*** Plasma p-tau for one individual Alzheimer's patient increased by 235%, which was not shown in the scatterplot.

***Fact:*** This patient's plasma p-tau increased by 38%, not 235%, as shown in a scatterplot.

***Fiction:*** Tissue staining showing Abeta42 inside neurons shows treatment effects.

***Fact:*** Yes, Abeta42 is indeed inside neurons prior to plaque formation.

***Fiction:*** The author's Citizen Petition to FDA dated August 18, 2021, is evidence of wrongdoing.

***Fact:*** Five days after the Citizen's Petition, Cassava Sciences announced it had reached an agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 studies of simufilam for the treatment of Alzheimer's disease. The SPAs underscore alignment with FDA on key scientific, clinical and regulatory requirements of the Company's Phase 3 program of simufilam in Alzheimer's disease. Furthermore, a Citizen's Petition allows any party to raise safety/efficacy concerns with drugs the FDA is considering for approval, which is not the case for Cassava Sciences' simufilam.

***Fiction:*** Extensive use of Western blot analysis is foundational to Cassava Sciences' research and therefore suspicious.

***Fact:*** Western blot analysis is foundational to the biotechnology industry. Western blotting is a standard lab technique used world-wide to detect a protein of interest.

**Fiction:** Cassava Sciences' Western blots data appear overexposed and highly processed, evidence of image manipulation.

**Fact:** High quality bands are supposed to look sharp. Smudged bands can be evidence of inexperience, depending on levels of protein in the band.

**Fiction:** Western blots data are identical, more evidence of image manipulation.

**Fact:** The Western blots bands shown in the allegation are control bands. Control bands are supposed to be highly similar (since they show equal amounts of protein between lanes). Bands show clear differences when expanded. In addition, image manipulation of control bands makes no sense since these would not change the end data.

**Fiction:** "Halo" effects in certain bands indicate fraud.

**Fact:** A "Halo" effects in certain bands is a direct result of very dense dark loading control bands.

**Fiction:** Unusual looking bands on Western blots were pieced together from multiple sources.

**Fact:** Proteins can and do stick to the side of a lane and migrate that way, resulting in 'candy-wrapper' appearance or other fictional images.

**Fiction:** Femtomolar binding affinity is unusual and suspicious.

**Fact:** Femtomolar binding affinity is a fundamental property of simufilam and may account for its relative potency and safety.

**Fiction:** Post-mortem brain tissue that is dead for a decade is unreliable.

**Fact:** Because of the inaccessibility of the human brain and its unavailability for biopsy, translational medicine can rely on post-mortem tissue. In our case, human brain tissue was collected within 6 hours of death, flash-frozen and stored at -80 Centigrade. This is a standard procedure for pathologists. Such tissue processing is also used in cancer and other fields. Cassava Sciences is not aware of an industry-wide 'expiration date' on human post-mortem brain tissue that is properly collected, processed and stored.

**Fiction:** Isoelectric focusing gels should not have crisp bands, which is evidence of fraud.

**Fact:** Quality isoelectric focusing gels often do have crisp bands.

**Fiction:** Changes in the Y-maze test for transgenic mice could be interpreted as a decline in cognition.

**Fact:** A panel of independent, peer-reviewers believe these changes represent an improvement, along with significant improvements in two other behavior tests.

**Fiction:** High-affinity binding of naloxone for filamin A is suspicious.

**Fact:** Naloxone binds the same site on filamin A. Of course, it will have high-affinity binding.

**Fiction:** Isoelectric focusing experiments indicate 100% of filamin A is in altered conformation in Alzheimer's disease and is largely restored to correct conformation by simufilam.

**Fact:** Cassava Sciences agrees. This nicely describes the mechanism of action for simufilam.

(Italicized emphasis added.)

128. Despite the Company's spin, the market received the news of August 24, 2021 and August 25, 2021 negatively, and the price per share of the Company's common stock dropped from \$117.83 at close on August 24, 2021—the citizen petition had not become public until after the markets had closed that day—to close August 25, 2021 at \$80.86. This \$36.97 decline marked approximately a 31.4% one-day decrease in value.

129. Still the Company's common stock remained artificially inflated because the Company's response contained false and misleading statements. Specifically, the Company's response on August 25, 2021 was false and misleading and failed to disclose that Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness. Quanterix merely conducted the biomarker tests which generated the raw data which the Company analyzed and synthesized into the form presented at the Alzheimer's Association International

Conference. Thus, the Company's framing of Quanterix's involvement as a shield to the allegation in the citizen petition that the Company misrepresented data was false and misleading.

**The Truth Fully Emerges**

130. On August 27, 2021, Quanterix issued a statement in response to Cassava, clarifying its involvement in the creation of the data the Company had presented at the Alzheimer's Association International Conference. Quanterix's statement said as follows, in relevant part:

***Cassava previously engaged Quanterix' Accelerator laboratory to perform sample testing based on blinded samples provided by Cassava. Quanterix or its employees did not interpret the test results or prepare the data charts presented by Cassava at the Alzheimer's Association International Conference (AAIC) in July 2021 or otherwise.***

Quanterix is widely recognized for its commitment to business integrity and to upholding the highest standards of quality. Quanterix' Simoa technology provides exquisite sensitivity for detecting and measuring biomarkers across a wide range of disease states, including neurology, oncology, and infectious disease. The Simoa technology has been trusted by 24 of the top 25 top pharmaceutical companies, and Quanterix customers have described the use of Simoa technology in over 1,300 research papers and presentations worldwide.

Quanterix harnesses the power of biomarkers with the latest detection solutions to enable a precision health vision of proactive, preventative healthcare and believes that, in doing so, can change the course of how diseases like Alzheimer's are currently studied and treated.

(Emphasis added.)

131. Cassava responded to Quanterix's above statement on the same day, August 27, 2021, by itself clarifying in a press release that:

***The Phase 2b clinical study was conducted by Cassava Sciences. Quanterix' sole responsibility with regard to this clinical study was to perform sample testing, specifically, to measure levels of p-tau in plasma samples collected from study subjects.***

***"To ensure data integrity, it is standard industry practice to keep separate the people who generate the data from the people who analyze the data," said Remi Barbier, President & CEO. "That certainly was the case here. Anything different is a distortion of the facts."***

Quanterix' sample testing was conducted entirely by its employees. Quanterix' employees were blind to treatment group, i.e., they did not know which samples were from placebo, or simufilam-treated patients. Quanterix conducted sample testing, then sent raw data to Cassava Sciences for analysis of treatment effects. Eventually, Cassava Sciences presented these data in a poster presentation at the Alzheimer's Association International Conference (AAIC) in July 2021. In keeping with scientific authorship guidelines, prior to submitting the abstract to AAIC, Cassava Sciences received permission from Quanterix to include its lab personnel in the author list.

(Emphasis added.)

132. On this news, the Company's share price declined by \$12.51 per share—approximately 17.7%—from its August 26, 2021 closing price of \$70.85 per share to close August 27, 2021 at \$58.34.

#### **DAMAGES TO CASSAVA**

133. As a direct and proximate result of the Individual Defendants' misconduct, Cassava has lost and will continue to lose and expend many millions of dollars.

134. Such expenditures include, but are not limited to, the fees associated with the Securities Class Actions filed against the Company and the Individual Defendants, and any internal investigations, and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

135. Such expenditures also include, but are not limited to, the costs incurred by the Company in undertaking any remedial measures in connection to it submitting manipulated data to the FDA.

136. Additionally, these expenditures include, but are not limited to, unjust compensation, benefits, and other payments provided to the Individual Defendants who breached their fiduciary duties to the Company.

137. As a direct and proximate result of the Individual Defendants' conduct, Cassava has also suffered and will continue to suffer a loss of reputation and goodwill, and a "liar's discount" that will plague the Company's stock in the future due to the Company's and their misrepresentations and the Individual Defendants' breaches of fiduciary duties and unjust enrichment.

### **DERIVATIVE ALLEGATIONS**

138. Plaintiff brings this action derivatively and for the benefit of Cassava to redress injuries suffered, and to be suffered, as a result of the Individual Defendants' breaches of their fiduciary duties as directors and/or officers of Cassava, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of the Exchange Act, and the aiding and abetting thereof.

139. Cassava is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

140. Plaintiff is, and has been at all relevant times, a shareholder of Cassava. Plaintiff will adequately and fairly represent the interests of Cassava in enforcing and prosecuting its rights, and, to that end, has retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

### **DEMAND FUTILITY ALLEGATIONS**

141. Plaintiff incorporates by reference and realleges each and every allegation stated above as if fully set forth herein.

142. A pre-suit demand on the Board of Cassava is futile and, therefore, excused. At the time of filing of this action, the Board consists of the following seven individuals: Defendants Barbier, Friedmann, Gussin, O'Donnell, Robertson, and Scannon (the "Director-Defendants"),

and nonparty Richard J. Barry (collectively with the Director-Defendants, the “Directors”). Plaintiff needs only to allege demand futility as to four of seven Directors who are on the Board at the time this action is commenced.

143. Demand is excused as to all of the Director-Defendants because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of the scheme they engaged in knowingly or recklessly to cause the Company to submit manipulated data to the FDA and to make and/or cause the Company to make false and misleading statements and omissions of material facts, which renders them unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

144. In complete abdication of their fiduciary duties, the Director-Defendants either knowingly or recklessly participated in the foregoing scheme. The fraudulent scheme was intended to make the Company appear more profitable and attractive to investors, with the Director-Defendants conducting a \$200 million stock offering at artificially inflated prices during the Relevant Period. Moreover, the Director-Defendants caused the Company to fail to maintain internal controls. As a result of the foregoing, the Director-Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

145. Additional reasons that demand on Defendant Barbier is futile follow. Defendant Barbier has served as the Company’s CEO, President, and Chairman of the Board since he founded the Company in May 1998. Thus, as the Company admits, he is a non-independent director. The Company provides Defendant Barbier with his principal occupation for which he receives substantial compensation. As CEO and President, Defendant Barbier was ultimately responsible for all of the false and misleading statements and omissions that were made during the Relevant

Period, including the statements he personally made in numerous press releases during the Relevant Period and the statements in the 2020 10-K, which he signed and signed SOX certifications. In addition, the 2021 Proxy Statement was solicited on his behalf, and the false and misleading statements contained therein contributed to his reelection to the Board and shareholders approving, on an advisory basis, his unjust compensation. As the Company's highest officer and as trusted Chairman of the Board, he conducted little, if any, oversight of the scheme to cause the Company to submit manipulated data to the FDA and to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Barbier is a defendant in each of the Securities Class Actions. For these reasons, Defendant Barbier breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

146. Additional reasons that demand on Defendant Friedmann is futile follow. Defendant Friedmann has served as a Company director since September 1998 and as the Company's CMO since 2001. Thus, as the Company admits, he is a non-independent director. The Company provides Defendant Friedmann with his principal occupation for which he receives handsome compensation. In particular, he is incapable to consider, independently and disinterestedly, causing the Company to take action against Defendant Barbier, who as CEO would be able to remove Defendant Friedmann from his principal occupation. In addition, Defendant Friedmann personally made false in misleading statement in multiple press releases during the Relevant Period and signed, and thus personally made, the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement was solicited on his behalf and the false and misleading statements contained therein contributed to shareholders approving, on



an advisory basis, his unjust compensation. As CMO and a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to submit manipulated data to the FDA and to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Friedman is a defendant in two of the three Securities Class Actions. For these reasons, Defendant Friedmann breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

147. Additional reasons that demand on Defendant Gussin is futile follow. Defendant Gussin has served as a Company director since March 2003. He also serves as a member of both the Audit Committee and the Compensation Committee. Defendant Gussin signed, and thus personally made, the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement, which contained false and misleading statements, was solicited on his behalf. As a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to submit manipulated data to the FDA and to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant Gussin breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

148. Additional reasons that demand on Defendant O'Donnell is futile follow. Defendant O'Donnell has served as a Company director since June 1998. Defendant O'Donnell signed, and thus personally made, the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement, which contained false and misleading statements, was

solicited on his behalf. As a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to submit manipulated data to the FDA and to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant O'Donnell breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

149. Additional reasons that demand on Defendant Robertson is futile follow. Defendant Robertson has served as a Company director since September 1998. He also serves as a member on each of the Audit Committee, the Compensation Committee, and Nominating and Governance Committee. In addition, he serves as Lead Director. Defendant Robertson signed, and thus personally made, the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement, was solicited on his behalf and the false and misleading statements contained therein contributed to his reelection to the Board. As a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to submit manipulated data to the FDA and to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant Robertson breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

150. Additional reasons that demand on Defendant Scannon is futile follow. Defendant Scannon has served as a Company director since December 2007. During the Relevant Period, he served as a member of the Audit Committee. Defendant Scannon signed, and thus personally made,

the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement, was solicited on his behalf and the false and misleading statements contained therein contributed to his reelection to the Board. As a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to submit manipulated data to the FDA and to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant Scannon breached his fiduciary duties, faces a substantial likelihood of liability

151. Additional reasons that demand on the Board is futile follow.

152. The Director-Defendants have longstanding business and personal relationships with each other and the Individual Defendants that preclude them from acting independently and in the best interests of the Company and the shareholders. For example, Defendants Scannon and Friedmann have prior experience working together from their overlapping time at XOMA Corporation, which Defendant Scannon founded. Moreover, Defendant Friedmann also worked together with Defendant Gussin at Johnson & Johnson. In addition, Defendants Barbier, Friedmann, O'Donnell, and Robertson, have worked together at the Company for over two decades since they all joined in 1998, with Defendant Gussin working with them for almost that long having joined in 2003. Defendants Scannon and Marsman have also worked with the Defendants Barbier, Friedmann, O'Donnell, Robertson, and Gussin at the Company for over a decade, with Defendant Scannon joining in 2007 and Defendant Marsman working at the Company for nearly ten years before leaving in 2012 but then rejoining in 2015. These conflicts of interest precluded the Director-Defendants from adequately monitoring the Company's operations and internal controls

and calling into question the Individual Defendants' conduct. Thus, demand upon the Director-Defendants would be futile.

153. Defendants Gussin, Robertson, and Scannon (the "Audit Committee Defendants") served as members of the Audit Committee during the Relevant Period. Pursuant to the Company's Audit Committee Charter, the Audit Committee Defendants are responsible for, *inter alia*, monitoring the Company's system of internal controls, reviewing their adequacy on an ongoing basis, and recommending to the Board remedies to any identified deficiencies. The Audit Committee Defendants failed to adequately oversee the Company's internal controls, failed to identify or remedy deficiencies with the Company's internal controls, and thus failed prevent the Company from issuing false and misleading statements to the public and the SEC. Thus, the Audit Committee Defendants breached their fiduciary duties, are not disinterested, and demand is excused as to them.

154. Defendants Gussin and Robertson (the "Compensation Committee Defendants") served as members of the Compensation Committee during the Relevant Period. As stated in the 2021 Proxy Statement, "[t]he Compensation Committee reviews and recommends to the Board of Directors the salaries, incentive compensation and benefits of the Company's officers and administers the Company's stock plans and employee benefit plans." The Compensation Committee Defendants thus reviewed and recommended to the Board the salaries, incentive compensation and benefits of the Individual Defendants, and awarded them compensation under the Company's stock plans. This compensation was unjust in light of the Individual Defendants'—including the Compensation Committee Defendants'—violations of law. Thus, the Compensation Committee Defendants breached their fiduciary duties, are not disinterested, and demand is excused as to them.

155. In violation of the Code of Ethics, the Director-Defendants conducted little, if any, oversight of the Company's engagement in the Individual Defendants' scheme to cause the Company to submit manipulated data to the FDA and to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, gross mismanagement, abuse of control, waste of corporate assets, unjust enrichment, and violations of the Exchange Act. In further violation of the Code of Ethics, the Director-Defendants failed to act with honesty and integrity; failed to provide the SEC and public with complete, fair, accurate, timely, and understandable disclosures; failed to comply with applicable laws and regulations; failed to act in good faith, responsibly with due care and diligence and without misrepresentation or omission of material facts; failed to promote ethical behavior at the Company; and failed to promptly report violations of the Code of Ethics. Thus, the Director-Defendants face a substantial likelihood of liability and demand is futile as to them.

156. Cassava has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Directors have not filed any lawsuits against the Individual Defendants or others who were responsible for that wrongful conduct to attempt to recover for Cassava any part of the damages Cassava suffered and will continue to suffer thereby. Thus, any demand upon the Directors would be futile.

157. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Director-Defendants can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable of

exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

158. The acts complained of herein constitute violations of fiduciary duties owed by Cassava's officers and directors, and these acts are incapable of ratification.

159. The Director-Defendants may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Cassava. If there is a directors' and officers' liability insurance policy covering the Directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Directors, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Directors were to sue the Director-Defendants or certain of the officers of Cassava, there would be no directors' and officers' insurance protection. Accordingly, the Directors cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Directors is futile and, therefore, excused.

160. If there is no directors' and officers' liability insurance, then the Directors will not cause Cassava to sue the Individual Defendants named herein, since, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

161. Thus, for all of the reasons set forth above, all of the Directors, and, if not all of them, at least four of the Directors, cannot consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

**FIRST CLAIM**

**Against the Director-Defendants for Violations of Section 14(a) of the Exchange Act**

162. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

163. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that “[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l].”

164. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. § 240.14a-9.

165. Under the direction and watch of the Director-Defendants, the 2021 Proxy Statement failed to disclose, *inter alia*: (1) contrary to the 2021 Proxy Statement’s descriptions of the Board’s risk oversight function and the Audit Committee’s responsibilities, the Board and its committees were not adequately exercising these functions, were causing or permitting the Company to submit manipulated data to the FDA and to issue false and misleading statements to the investing public, and thus the Individual Defendants on the Board were breaching their fiduciary duties; and (2) the Individual Defendants on the Board who were breaching their

fiduciary duties were improperly interested in increasing their unjust compensation by seeking shareholder approval of the amendment to the 2018 Plan, which the Individual Defendants serving on the Compensation Committee were improperly administering by rewarding misconduct. The 2021 Proxy Statement further failed to disclose that: (1) the quality and integrity of the data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; (5) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (6) the Company failed to maintain internal controls. As a result, the 2021 Proxy Statement was materially false and misleading.

166. In the exercise of reasonable care, the Director-Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2021 Proxy Statement was materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the 2021 Proxy Statement, including but not limited to, the reelection of Defendants Barbier, Robertson, and Scannon to the Board; approving an amendment to the 2018 Plan; ratifying Ernst & Young LLP as independent auditor for the fiscal year ending December 31, 2021; and the approval, on an advisory basis, of Defendants Barbier's, Friedmann's, and Schoen's compensation.

167. The false and misleading elements of the 2021 Proxy Statement led to, among other things, the reelection of the Defendants Barbier, Robertson and Scannon, which allowed them to continue to breach their fiduciary duties to the Company. The false and misleading elements of the



2021 Proxy Statement also led the Company's shareholders to approve, on an advisory basis, Defendants Barbier's, Friedmann's, and Schoen's compensation.

168. The Company was damaged as a result of the Director-Defendants' material misrepresentations and omissions in the 2021 Proxy Statement.

169. Plaintiff, on behalf of Cassava, has no adequate remedy at law.

## **SECOND CLAIM**

### **Against the Individual Defendants for Breach of Fiduciary Duties**

170. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

171. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Cassava's business and affairs.

172. Each of the Individual Defendants violated and breached his fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

173. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Cassava.

174. In breach of their fiduciary duties owed to Cassava, the Individual Defendants caused or permitted the Company to submit manipulated data to the FDA.

175. Additionally, in breach of their fiduciary duties, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and/or misleading statements and/or omissions of material fact that failed to disclose, *inter alia*, that: (1) the quality and integrity of the data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held

out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; (5) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (6) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (7) the Company failed to maintain internal controls. As a result of the foregoing, Cassava's public statements touting its partnerships, preorders, and internal controls were materially false and misleading at all relevant times.

176. The Individual Defendants further failed to correct and/or caused the Company to fail to correct the false and misleading statements and omissions of material fact, which renders them personally liable to the Company for breaching their fiduciary duties.

177. Also in breach of their fiduciary duties, the Individual Defendants caused the Company to fail to maintain internal controls.

178. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent scheme set forth herein and to fail to maintain internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent scheme and to fail to maintain adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Cassava's securities.

The Individual Defendants, in good faith, should have taken appropriate action to correct the scheme alleged herein and to prevent it from continuing to occur.

179. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

180. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Cassava has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

181. Plaintiff on behalf of Cassava has no adequate remedy at law.

### **THIRD CLAIM**

#### **Against the Individual Defendants for Unjust Enrichment**

182. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

183. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Cassava.

184. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Cassava that was tied to the performance or artificially inflated valuation of Cassava, or received compensation or other payments that were unjust in light of the Individual Defendants' bad faith conduct.

185. Plaintiff, as a shareholder and a representative of Cassava, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, including from insider transactions, the redemption of preferred stock, benefits, and other compensation, including any performance-based or valuation-based compensation, obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

186. Plaintiff on behalf of Cassava has no adequate remedy at law.

**FOURTH CLAIM**

**Against the Individual Defendants for Abuse of Control**

187. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

188. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Cassava, for which they are legally responsible.

189. As a direct and proximate result of the Individual Defendants' abuse of control, Cassava has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

190. Plaintiff on behalf of Cassava has no adequate remedy at law.

**FIFTH CLAIM**

**Against the Individual Defendants for Gross Mismanagement**

191. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

192. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Cassava in a manner consistent with the operations of a publicly-held corporation.

193. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Cassava has sustained and will continue to sustain significant damages.

194. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

195. Plaintiff on behalf of Cassava has no adequate remedy at law.

**SIXTH CLAIM**

**Against the Individual Defendants for Waste of Corporate Assets**

196. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

197. The Individual Defendants caused the Company to pay the Individual Defendants excessive salaries and fees, to the detriment of the shareholders and the Company.

198. As a result of the foregoing, and by failing to properly consider the interests of the Company and its public shareholders, the Individual Defendants have caused Cassava to waste valuable corporate assets, to incur many millions of dollars of legal liability and/or costs to defend unlawful actions, to engage in internal investigations, and to lose financing from investors and business from future customers who no longer trust the Company and its products.

199. As a result of the waste of corporate assets, the Individual Defendants and are each liable to the Company.

200. Plaintiff on behalf of Cassava has no adequate remedy at law.

**SEVENTH CLAIM**

**Against Defendants Barbier, Schoen, Kupiec, Friedmann, and Marsman for Contribution Under Sections 10(b) and 21D of the Exchange Act**

201. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

202. Cassava, and Defendant Barbier, Schoen, Kupiec, Friedmann, and Marsman are named as defendants in the Securities Class Actions,<sup>2</sup> which assert claims under the federal

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<sup>2</sup> Along with the Company, Defendants Barbier and Schoen are named as defendants in all three of the Securities Class Action, while Defendants Kupiec, Friedmann, and Marsman are named as defendants in two of the three Securities Class Actions.

securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Actions for these violations of the federal securities laws, the Company's liability will be in whole or in part due to Defendants Barbier's, Schoen's, Kupiec's, Friedmann's, and Marsman's willful and/or reckless violations of their obligations as officers and/or director of Cassava.

203. Defendants Barbier, Schoen, Kupiec, Friedmann, and Marsman, because of their positions of control and authority as CEO and Chairman, CFO, CCDO, CMO, and consultant and Senior Vice President of Regulatory Affairs of Cassava, respectively, were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of Cassava, including the wrongful acts complained of herein and in the Securities Class Actions.

204. Accordingly, Defendants Barbier, Schoen, Kupiec, Friedmann, and Marsman are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

205. As such, Cassava is entitled to receive all appropriate contribution or indemnification from Defendants Barbier, Schoen, Kupiec, Friedmann, and Marsman.

#### **PRAYER FOR RELIEF**

FOR THESE REASONS, Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows:

- (a) Declaring that Plaintiff may maintain this action on behalf of Cassava, and that Plaintiff is an adequate representative of the Company;
- (b) Declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Cassava;

(c) Determining and awarding to Cassava the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

(d) Directing Cassava and the Individual Defendants to take all necessary actions to reform and improve Cassava's corporate governance and internal procedures to comply with applicable laws and to protect Cassava and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Certificate of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies:

1. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the board;

2. a provision to permit the shareholders of Cassava to nominate at least four candidates for election to the Board;

3. a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations;

(e) Awarding Cassava restitution from Individual Defendants, and each of them;

(f) Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

(g) Granting such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Dated: November 4, 2021

Respectfully submitted,

**STECKLER WAYNE COCHRAN  
CHERRY PLLC**

By: /s/ Braden M. Wayne

Braden M. Wayne

Texas Bar No. 24075247

Stuart L. Cochran

Texas Bar No. 24027936

12720 Hillcrest Rd, Suite 1045

Dallas, Texas 75230

Telephone: (972) 387-4040

Email: stuart@swclaw.com

Email: braden@swclaw.com

**THE ROSEN LAW FIRM, P.A.**

Phillip Kim

275 Madison Avenue, 40th Floor

New York, NY 10016

Telephone: (212) 686-1060

Facsimile: (212) 202-3827

Email: pkim@rosenlegal.com

**THE BROWN LAW FIRM, P.C.**

Timothy Brown

767 Third Avenue, Suite 2501

New York, NY 10017

Telephone: (516) 922-5427

Facsimile: (516) 344-6204

Email: tbrown@thebrownlawfirm.net

*Counsel for Plaintiff*